

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL)
a corporation of Barbados,)
Plaintiff,) C.A. No. 05-730
v.)
ANDRX PHARMACEUTICALS, LLC and)
ANDRX CORPORATION,)
Defendants.)
75 OCT 14 2005
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COMPLAINT FOR PATENT INFRINGEMENT

For its complaint herein, Plaintiff alleges as follows:

1. Plaintiff Biovail Laboratories International SRL ("Biovail") is a corporation organized and existing under the laws of Barbados and has a place of business in Carolina, Puerto Rico.
2. Upon information and belief, defendant Andrx Pharmaceuticals, LLC ("Andrx LLC") is a limited liability company organized under the laws of Delaware, and maintains a principal place of business at 4955 Orange Drive, Davie, Florida 33314.
3. Upon information and belief, Andrx LLC is a wholly-owned subsidiary of Andrx Corporation ("Andrx Corp."), a corporation organized under the laws of Delaware that maintains a principal place of business at 4955 Orange Drive, Davie, Florida 33314.
4. Upon information and belief, Andrx LLC and Andrx Corp. have common officers and directors; the acts of Andrx LLC complained of herein were done at

the direction of, with the authorization of, and with the cooperation, participation and assistance of Andrx Corp.

5. Andrx LLC and Andrx Corp. are referred to hereinafter collectively as "Andrx."

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America and specifically under 35 U.S.C. § 271(e) and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

7. Upon information and belief, Andrx, including through subsidiaries, sells various products and does business throughout the United States including this District, and both Defendants are organized under the laws of Delaware.

8. Upon information and belief, Andrx manufactures bulk pharmaceuticals and pharmaceutical products that are sold and used, including through subsidiaries, throughout the United States, including this District.

CLAIM FOR RELIEF

9. Bioavail incorporates paragraphs 1-8 by reference herein.

10. United States Patent No. 5,529,791 (hereinafter "the '791 patent") was lawfully granted on June 25, 1996 to Galephar P.R., Inc., Ltd. ("Galephar"), the assignee of the named inventors, Arthur M. Deboeck and Philippe R. Baudier.

11. A copy of the '791 patent is attached as Exhibit A.

12. Biovail is the exclusive licensee of the '791 patent under a September, 1995 Agreement, which remains in full force and effect, and has the exclusive right to sublicense others and to sue for infringement.

13. Biovail is the holder of New Drug Application ("NDA"), No. 21-392, by which the United States Food & Drug Administration ("FDA") first granted approval for 120, 180, 240, 300, 360 and 420 mg extended release tablets including the active ingredient diltiazem hydrochloride. These tablets are marketed in the United States under the tradename Cardizem® LA, and are indicated for the treatment of hypertension, and the management of chronic stable angina.

14. Upon information and belief, Andrx filed in the FDA an Abbreviated New Drug Application ("ANDA") No. 77-686 including a certification with respect to the '791 patent under § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to market and sell a generic version of Cardizem® LA 420 mg tablets prior to the expiration of that patent.

15. Upon information and belief, on or about June 22, 2005, Andrx sent a notice letter to Biovail, Galephar, and to Bank of Nova Scotia in which Andrx represented that it had filed an ANDA for a generic version of Cardizem® LA 420 mg tablets, and that it sought approval of its ANDA prior to the expiration of the '791 patent. Biovail received a copy of Andrx's notice letter on or about June 27, 2005.

16. On August 10, 2005, within 45 days of receipt of Andrx's June 22, 2005 notice letter, Biovail brought suit against Andrx in this Court for infringement under 35 U.S.C. § 271(e).

17. Upon information and belief, Andrx filed in the FDA an amendment to ANDA No. 77-686 including a certification with respect to the '791 patent under § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to market and sell generic versions of Cardizem® LA 120, 180, 240, 300, and 360 mg tablets prior to the expiration of that patent.

18. Upon information and belief, on or about August 30, 2005, Andrx sent a notice letter to Biovail, Galephar, and to Bank of Nova Scotia in which Andrx represented that it had filed an amendment to ANDA No. 77-686 for generic versions of Cardizem® LA 120, 180, 240, 300, and 360 mg tablets ("Amended ANDA"), and that it sought approval of its Amended ANDA prior to the expiration of the '791 patent. Biovail received a copy of Andrx's notice letter on or about September 2, 2005.

19. Upon information and belief, the Andrx products that are the subjects of its amendment to ANDA No. 77-686 will contain beads that will be compressed with other excipients into tablets. On further information and belief, by virtue of the tableting process, beads of the Andrx products will contain an effective amount of a wetting agent in admixture with one or more diltiazem salts.

20. Because Andrx seeks approval of its Amended ANDA to engage in the commercial manufacture, use or sale of a drug product claimed in the '791 patent before its expiration, Andrx has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A).

21. Biovail is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Andrx's Amended ANDA be a date that is not earlier than the expiration date for the '791 patent,

or any later expiration of exclusivity for the '791 patent to which Biovail is or becomes entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter a Judgment that:

- a. Andrx infringed one or more claims of the '791 patent by submitting the aforesaid Amended ANDA;
- b. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Andrx, its affiliates and subsidiaries, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, and their successors or assigns, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compounds claimed in the '791 patent;
- c. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Andrx's Amended ANDA No. 77-686 be a date that is not earlier than the expiration date for the '791 patent, or any later date of exclusivity to which Plaintiff is or becomes entitled;
- d. To the extent Andrx has committed any acts with respect to the compounds claimed in the '791 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), Plaintiff be awarded damages for such acts; and

e. For such other and further relief as the Court may deem just and proper under the circumstances.

MORRIS, NICHOLS, ARSHT & TUNNELL



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October 14, 2005

EXHIBIT A





United States Patent [19]
Deboeck et al.

[11] Patent Number: 5,529,791
[45] Date of Patent: Jun. 25, 1996

[54] EXTENDED RELEASE FORM OF DILTIAZEM

[58] Field of Search 424/457, 458, 424/452, 490, 493, 497, 498, 499, 494

[73] Inventor: Arthur M. Deboeck, Gurabo, Puerto Rico; Philippe R. Baudier, Waterloo, Belgium

[56] References Cited

U.S. PATENT DOCUMENTS

5,112,621 5/1992 Savona et al. 424/497
5,275,624 1/1994 Carl et al. 424/490

Primary Examiner—Thomann K. Page
Assistant Examiner—James M. Spear
Attorney, Agent, or Firm—Obisca, Spivak, McClelland,
Miller & Neustadt

[73] Assignee: Calephar P.R., Inc., Ltd. Carolina, Puerto Rico

[57] ABSTRACT

[21] Appl. No.: 311,722

An extended-release galenical form of Diltiazem or a pharmaceutically acceptable salt thereof, which comprises beads comprising said Diltiazem or a pharmaceutically acceptable salt thereof as an active ingredient and a wetting agent, said beads being coated with a microporous membrane comprising at least a water-soluble or water-dispersible polymer or copolymer and a pharmaceutically acceptable adjuvant.

[22] Filed: Sep. 23, 1994

4 Claims, 2 Drawing Sheets

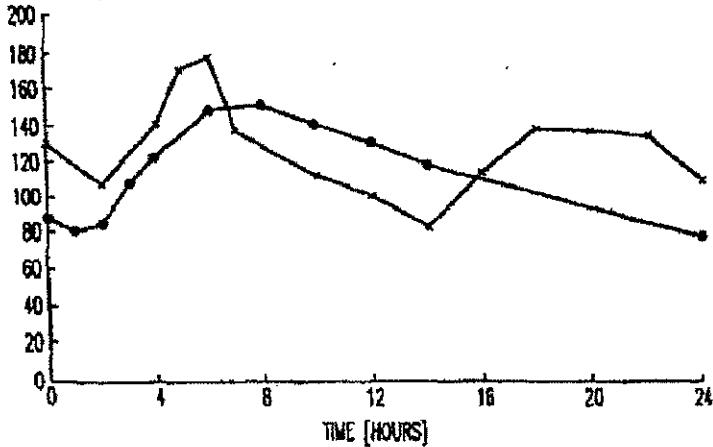
Related U.S. Application Data

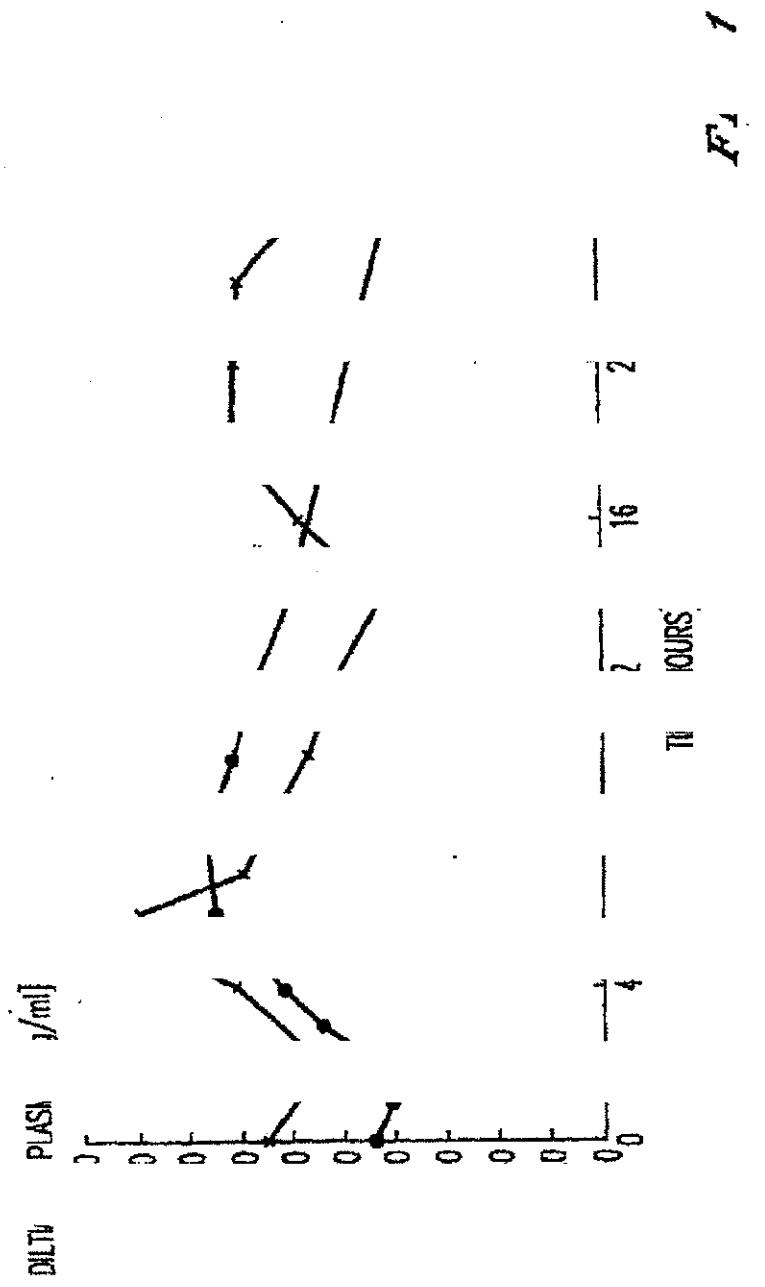
[63] Continuation of Ser. No. 61,351, May 28, 1993, abandoned, which is a continuation of Ser. No. 721,396, Jun. 25, 1991, Pat. No. 5,284,505.

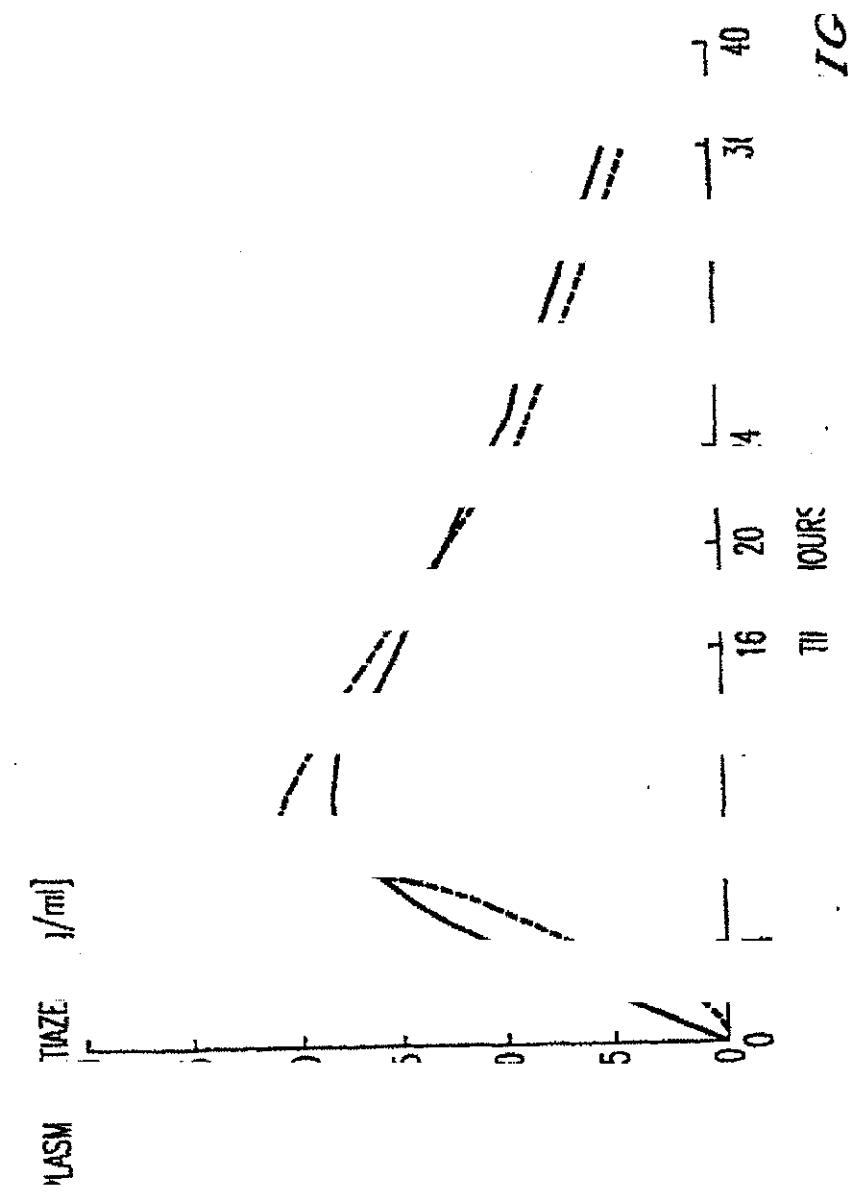
[51] Int. Cl.® A61K 9/16; A61K 9/58;
A61K 9/62

[52] U.S. Cl. 424/494; 424/490; 424/497;
514/777; 514/783; 514/786; 514/970

DILTIAZEM PLASMA [ng/ml]







I
EXTENDED RELEASE FORM OF
DILTIAZEM

As a continuation of application No. 5,288,505
Jun. 26, 1991, now U.S. Pat. No. 5,288,505.

אודות אוניברסיטת סטנפורד וו' רשות הון וטכניון

of Diltiazem, a process for the manufacture thereof and pharmaceutical compositions containing the same.

2 Description of the Background

such as propranolol or the calcium channel blockers, hypertension; either alone or in combination with other medications.

increasing intracellular calcium concentration to cardiac and vascular smooth muscle cells, coronary arteries, peripheral arteries and arterioles are dilated and heart rate may be

For diseases which require continuous and constant care.

and, such as *Hummerichia* and *marica decora*. Dilatation

annoying or even impossible to effect, particularly during the night. Further, after each administration of an immediate-release galenic form of Diliazem, which generally is

organ, more particularly the heart, are alternately subjected to overdoes and to underdoses of medicine.

In order to alleviate these drawbacks, a first generic form

Although this term covers a reduction in peak concentrations and in the number of daily intakes from 4 to 2, it does not eliminate high Dihydrogen blood concentration between successive intakes. The evidence is still valid.

200 layers so as to obtain a core which, thereafter, requires between 20 and 40 layers of coating so as to obtain the membrane. Moreover, the solvent of the polymer solution

flammability and toxicity. Such solvents are also environmentally hazardous. Particular care must be taken to avoid any traces of solvent in the final product because the

Thus, a need condynce to exist for a multiple unit extended-release diflunisal hydrochloride galenical form which need be administered only once daily, and from which

SUMMARY OF THE INVENTION

It is also an object of this invention to provide galenic forms of Diltiazem having excellent bioavailability while avoiding plasma concentration peaks.

acceptable salt of Dilizem, which comprises beads containing the pharmaceutically acceptable salt of Dilizem as an active ingredient and a wetting agent, said beads being

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates the effect of the present invention to

FIG. 2 illustrates in the solid curve, the mean plasma concentration of the drug versus time.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Widokom - 1924-11-01/Arbeitsamt Lübeck/Hinrichsen

corresponding to U.S. Pat. No. 3,562,257.

The present invention relates to novel galenic forms of Nitrophen being characterized by having an extended re-

raises plasma concentrations in a desired, effective range while simplifying the administration of the medicine to only once daily.

a pharmaceutically acceptable salt of Diltiazem as an active substance, associated with at least a wetting agent, the beads being covered with a microporous membrane constituted by

In accordance with the present invention, any pharmaceutically acceptable salt of Diltiazem may be prepared in

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4

In more detail, the microporous membrane wherof the Dilizem containing microgranules are covered, is constituted by a mixture of a water-soluble and/or water-dispers-

expressed by the percentage of the coating applied to the uncoated beads.

The weight of the microporous membrane may be 2 to

The active substance containing beads are presented in 10 form of spheres the diameter of which is between about 0.5 mm and 2 mm, preferably between about 0.1 mm and

weight. The microporous membrane may contain 5 to 95% and, preferably, 30 to 90% of polymer, polymer mixture or copolymer.

or salt mixture or the osmotic, the suspending components may more particularly be exemplified: sucrose, mannitol, sorbitol;

such as the hydrochloride, and at least a wetting agent, coated with at least one polymer-based microporous membrane, the coated beads being contained in capsules, little

under the name of sucrosates (Gattefosse, France) or under the name of crostobates (Croda, U.K.);

extended-release in the gastro-intestinal tract, and process entailing preparing beads and coating the same with a single microporous membrane.

and emulgines, repectively;

so-called fatty acid esters (Span, Atish, U.S.A.);

polyglycidic-glycidic and polyglycidic-alcohol esters

wetting agents) in a mixture or binary mixture form, or in solution, in the presence of a solvent, such as water, so as to obtain an extrudable paste or plastic mass. Said paste is

Microcrystalline celluloses, such as Avicel products (PMC, U.S.A.); methylcelluloses, carboxymethylcelluloses, hydroxyethylcelluloses (Natrosol, Hercules, U.S.A.),

microspheres or beads from the calindol product provided in the form of spaghetti, an apparatus called "spaghetti" (ATMATA (R) (Belgian) or MARUMERIZER (SPLIHL)).

polymers or copolymers constituting the microporous membrane, may be mentioned particularly polyacrylates and polymethacrylates of the Eudragit type, such as Eudragit

agglomeration of the Dilizem or salt thereof, such as the chlorhydrate, contingently mixed to at least a wetting agent with a dimension or solution of at least one wetting

hydroxypropylmethylcellulose and their derivations.

dry granulator such as the collette (Belgium) type.

These polymers or copolymers may be associated into the microporous membrane with at least one adjuvant as exempl-

The obtained beads are dried by any means, for example in an oven or by means of a gas in a fluidized bed.

polypropyleneglycols and polyvinylpyrrolidones;

pigments, such as iron oxides and titanium oxide;

fillers, such as talc and magnesium

means of anyone of the above described techniques, may contain the following weight proportions of the Dilizem or salt thereof, wetting agents and carriers or excipients:

derived from sorbitol possibly containing polyoxyethylene chains, preferably surfactive agents of the Tween type, namely Tween 80 as well as polyethoxylated sorbitol;

PMC, U.S.A.,

2 to 10% Methocel E 5 (hydroxypropylmethylcellulose of DOW, U.S.A.);

is associated to the polymer or copolymer, the microporous membrane contains, preferably, talc and/or magnesium stearate as a lubricant, polyvinylpyrrolidone as a plasticifying

agent, polyethylene glycols and/or polyvinylpyrrolidone and at least one of the above-named polymers and at least one of the above-mentioned adjuvants onto said beads. This pal-

verization may be carried out by spray-granulating or by pulverizing the above-named dispersion into a turbine or fluidized bed.

comprised between 0.7 mm and 1.4 mm are retained. 1,179 g of beads were obtained yield (84%).

In general, from about 120 mg to about 480 mg per day of Dilatene salt is administered per day per patient in total. Additionally, the extended release form composition of

Orudite P 100	39.3 g
Microcrystalline cellulose (Avicel pH 101)	70 g
Povidone K 30	100 g

with the Dilatene salt.

For example, other pharmaceutically active ingredients, such as β -adrenoceptor blocking agents or diuretics may be

ml water USP is added and the mixing is pursued during 10 minutes more until a plastic mass is obtained. This mass is then extruded through a Full Paudal extruder combined with

such as Propranolol, Atenolol, Labetalol, Timolol. ¹⁴ Solisol may be used, for example.

As examples of diuretic agents, drugs such as Hydrochlorothiazide, Furosemide, and Ethacrynic acid.

at 60° C, the beads are sieved so as to eliminate the ones with a size larger than 1.4 mm and with a size smaller than 0.7 mm. The amount of beads obtained with size comprised

not be.

The present invention will now be further illustrated by references to certain examples, which are provided solely for

Beads prepared in Example 1 were coated in a STREA-1 (Aromatic) fluidized bed using the "Top spraying" technic.

starting from an aqueous dispersion which contains by weight:

10 to 70 Eudragit E901D (polymer)

Coating suspension composition:

Macrodex 5000	12.5 g
water	100.0 g
Smoothon	1.0 g
Twez 50	0.8 g

0.5 to 15% polyvinylpyrrolidone (plasticizing agent);
0.01 to 2% silicone oil (antifoaming agent);
0.05 to 5% polysorbate 20 (wetting agent)

The present invention will now be further illustrated by references to certain examples, which are provided solely for

nd dilution medium consisted of a phosphate buffer pH 5.6 and the revolution speed 100 rpm.

paring the same, therapeutic applications thereto and pharmaceutical controls using the present galenic forms.

5	52
12	54

Dilatene hydrochloride
Lecithin
Microcrystalline cellulose (Avicel pH 101)
Povidone K 30

112.0 g
119 g
140 g
27 g

100 beads in an example a 3000 ml/min. using a rotating bed coater equipped with a "water" system. 8 kg of uncoated beads were introduced in an Aromatic Autocoker

granulating same though the obtained plastic mass is extruded through a cylinder with 1 mm diameter holes (Alexanderwerk). The small cylinders are rounded, so as to

Coating suspension:

Macrodex 5000	0.635 kg
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Hydroxypropylmethylcellulose
Polyacrylic Acid
Sodiumcitraat
Eudragit NE 30 D

0.007 kg
0.018 kg
12.4 kg

5

Cardizem SR® after a twice daily administration.

Fourth, the time during the concentration is above 75% of the maximum concentration is 46% longer after the once

The results were obtained using the same equipment as in Example 3. The dissolution medium was composed of 900 ml of water and the temperature was maintained of 37±0.5°

10 The product of Example 4 was given to 24 healthy volunteers and the bioavailability was measured after single oral dose of 300 mg given with and without food.

chewed time [h]	percent dissolved [%]
2	9
4	33

15 experiment was repeated in the same subjects with the other treatment at an interval of 7 days. The plasma concentration of Diltiazem was determined in all available samples using

Pharmacokinetic results

The new galenic form of Example 4 was the object of a pharmacokinetic study in comparison with a form in

20 ence and measurement of bioequivalence. FIG. 2 curves shows the mean plasma levels obtained when the product is taken without food and the dotted curve the mean plasma

the 2 products. The product of Example 4 was administered at a dose of 300 mg once daily while the product on the market was administered twice daily at a dose of 150 mg.

Pharmacokinetics parameter - product of Example 4

	Without food	With food	Without food	With food
Area under the curve (0-24 h)	mg.h/ml	2742 ± 107	2864 ± 1222	mg.h/ml
Maximum	mg/ml	116.5 ± 54.1	191.7 ± 85.3	mg/ml
Time during the concentration is above 75% of the maximum	h	9.8 ± 2.3	6.7 ± 3.7	h

25 Example 4 given with food is bioequivalent to the administration without food to within less than 20% regarding area under the curve, mean residence time and maximum con-

area.

FIG. 1

30 From all the results it appears clearly that the product of the present invention can be administered once a day and that the plasma concentration variations are lower than the

Area under the curve (0-24 h)	mg.h/ml	2742 ± 107	2864 ± 1222
Maximum	mg/ml	116.5 ± 54.1	191.7 ± 85.3

35 apparent to one skilled in the art that many changes and modifications may be made to the above-described embodiments while remaining within the spirit and the scope of the

FIG. 1

40 An enteric-release galenic composition in the form of more pharmaceutically-acceptable salts of Diltiazem which comprises beads containing an effective amount of one or

45 First, FIG. 1 shows that the Diltiazem plasma levels obtained after a once daily administration of one of the

50 5. An enteric-release galenic composition in the form of more pharmaceutically-acceptable salts of Diltiazem in each bead, ensuring that the solubility of the Diltiazem is unaffected by the pH of the gastrointestinal tract

55 Diltiazem, the bioavailability, expressed by the area under the curve of the 3 products, is equivalent (no statistical detectable difference).

or other adverse conditions which the composition will meet therein, said beads being coated with a microporous membrane comprising at least a water-soluble or water-dispers-

2. The composition of claim 1, wherein the wetting agent is a sugar.

3. The composition of claim 1, wherein the effective

and wherein the wetting agent is selected from the group consisting of sugars, C₁-C₂₀ fatty acid esters of sucrose or sucrose, glycerides of sucrose, fatty acid

4. The composition of claim 1, wherein the wetting agent is sucrose stearate, the water-soluble or water-dispersible polymer or copolymer is hydroxypropylmethyl-cellulose

ide-polyglycides, lecithins and a combination thereof.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVAIL LABORATORIES INTERNATIONAL SRL)
a corporation of Barbados,)
Plaintiff,)
v.)
ANDRX PHARMACEUTICALS, LLC and)
ANDRX CORPORATION,)
Defendants.)

C.A. No. 730

2005 OCT 14 FILED 3PM

PLAINTIFF'S RULE 7.1. DISCLOSURE STATEMENT

Pursuant to Fed. R. Civ. P. 7.1(a), the undersigned counsel for Biovail Laboratories International SRL, which is a non-governmental corporate party, certifies that Biovail Laboratories International SRL is a wholly-owned subsidiary of Biovail Corporation and there is no publicly held corporation that owns 10% or more of the stock of Biovail Corporation.

MORRIS, NICHOLS, ARSHT & TUNNELL



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October 14, 2005

SAO 85 (Rev. 8/98) Notice, Consent, and Order of Reference — Exercise of Jurisdiction by a United States Magistrate Judge

UNITED STATES DISTRICT COURT

District of _____

Plaintiff
v.NOTICE, CONSENT, AND ORDER OF REFERENCE —
EXERCISE OF JURISDICTION BY A UNITED STATES
MAGISTRATE JUDGE

Defendant

Case Number:

(5 - 7 3 0 -

NOTICE OF AVAILABILITY OF A UNITED STATES MAGISTRATE JUDGE
TO EXERCISE JURISDICTION

In accordance with the provisions of 28 U.S.C. §636(c), and Fed.R.Civ.P. 73, you are notified that a United States magistrate judge of this district court is available to conduct any or all proceedings in this case including a jury or nonjury trial, and to order the entry of a final judgment. Exercise of this jurisdiction by a magistrate judge is, however, permitted only if all parties voluntarily consent.

You may, without adverse substantive consequences, withhold your consent, but this will prevent the court's jurisdiction from being exercised by a magistrate judge. If any party withholds consent, the identity of the parties consenting or withholding consent will not be communicated to any magistrate judge or to the district judge to whom the case has been assigned.

An appeal from a judgment entered by a magistrate judge shall be taken directly to the United States court of appeals for this judicial circuit in the same manner as an appeal from any other judgment of this district court.

CONSENT TO THE EXERCISE OF JURISDICTION BY A UNITED STATES MAGISTRATE JUDGE

In accordance with provisions of 28 U.S.C. §636(c) and Fed.R.Civ.P. 73, the parties in this case consent to have a United States magistrate judge conduct any and all proceedings in this case, including the trial, order the entry of a final judgment, and conduct all post-judgment proceedings.

Party Represented

Signatures

Date

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

ORDER OF REFERENCE

IT IS ORDERED that this case be referred to _____ United States Magistrate Judge, to conduct all proceedings and order the entry of judgment in accordance with 28 U.S.C. §636(c) and Fed.R.Civ.P. 73.

Date _____

United States District Judge _____

NOTE: RETURN THIS FORM TO THE CLERK OF THE COURT ONLY IF ALL PARTIES HAVE CONSENTED
ON THIS FORM TO THE EXERCISE OF JURISDICTION BY A UNITED STATES MAGISTRATE JUDGE.



CORPORATION SERVICE COMPANY

Notice of Service of Process

CXT / ALL
 Transmittal Number: 4206236
 Date Processed: 10/18/2005

Primary Contact: Rob Goldfarb Esq.
 Andrx Corporation
 8151 Peters Road
 Floor 4th
 Plantation, FL 33324

Copy of transmittal only sent to: Ms. Karina de Windt

Entity:	Andrx Corporation Entity ID Number 1980756
Entity Served:	Andrx Corporation
Title of Action:	Biovail Laboratories International SRL vs. Andrx Pharmaceuticals, LLC
Document(s) Type:	Summons/Complaint
Nature of Action:	Trademark / Copyright / Patent
Court:	United States District Court , Delaware
Case Number:	05-780
Jurisdiction Served:	Delaware
Date Served on CSC:	10/18/2005
Answer or Appearance Due:	20 Days
Originally Served On:	CSC
How Served:	Personal Service
Plaintiff's Attorney:	Jack B. Blumenfeld 302-658-9200

Information contained on this transmittal form is for record keeping, notification and forwarding the attached document(s). It does not constitute a legal opinion. The recipient is responsible for interpreting the documents and taking appropriate action.

To avoid potential delay, please do not send your response to CSC
2711 Centerville Road Wilmington, DE 19808 (888) 690-2882 | sop@cscinta.com

AO 440 (Rev. 10/93) Summons in a Civil Action

United States District Court

DISTRICT OF DELAWARE

BIOVAL LABORATORIES INTERNATIONAL SRL

SUMMONS IN A CIVIL ACTION

Plaintiff,

v.

ANDRX PHARMACEUTICALS, LLC, and
ANDRX CORPORATION,

CASE NUMBER: 10-14-735

Defendants.

TO: Andrx Corporation
c/o Corporation Service Company
2711 Centerville Road
Suite 400
Wilmington, DE 19808

YOU ARE HEREBY SUMMONED and required to file with the Clerk of this Court and serve upon

PLAINTIFF'S ATTORNEY:

Jack B. Blumenfeld, Esquire
Morris, Nichols, Arشت & Tunnell
1201 N. Market Street, P.O. Box 1347
Wilmington, DE 19899-1347

an answer to the complaint which is herewith served upon you, within twenty (20) days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

PETER T. DALLEO

CLERK

10-14-05

DATE

By *Bet* [initials]
BY DEPUTY CLERK

AO 440 (REV. 10/93) Summons in a Civil Action

RETURN OF SERVICE

Service of the Summons and amended complaint was made by me ¹	DATE
NAME OF SERVER (PRINT)	TITLE

Check one box below to indicate appropriate method of service

Served personally upon the defendant. Place where served: _____

Left copies thereof at the defendant's dwelling house or usual place of abode with person of suitable age and discretion then residing therein. Name of person with whom the summons and complaint were left: _____

Returned unexecuted: _____

Other (specify): _____

STATEMENT OF SERVICE FEES

TRAVEL	SERVICES	TOTAL

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.

Executed on _____

Date

Signature of Server

Address of Server

¹) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure